DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

February 12, 2015

Teleflex Medical, Inc.
Mr. Brian Gall
Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K143469
Trade/Device Name: SOFTECH® Plus $ETCO_2$ Cannula
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK, CAT
Dated: January 12, 2015
Received: January 13, 2015

Dear Mr. Gall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143469

Device Name
SOFTECH® Plus ETCO2 Cannula

Indications for Use *(Describe)*
The Hudson RCI SOFTECH® Plus ETCO2 Nasal Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen to a patient while providing a means to sample expired gas. It is intended for use in patients requiring oxygen therapy to improve blood oxygen levels while monitoring expired gas to determine ventilatory rate.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) SUMMARY

### A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-544-8000 x 682514
Fax: 919-361-3914

### B. Contact Person

Brian Gall
Regulatory Affairs Specialist

### C. Date Prepared

December 3, 2014

### D. Device Name

| | |
|---|---|
| Trade Name: | SOFTECH® Plus $ETCO_2$ Cannula |
| Classification Name: | Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase |
| Product Code: | CCK, CAT |
| Regulation Number: | 868.1400 |
| Classification: | II |
| Classification Panel: | Anesthesiology |

### E. Predicate Device

This submission demonstrates substantial equivalence to the predicate device SOFTECH® Plus $ETCO_2$ Cannula – K132946, with the addition of a shelf-life.

### F. Device Description

The SOFTECH Plus $ETCO_2$ Cannula is a non-sterile disposable, single patient use device that acts as an adjunct to oxygen therapy with its primary function providing a means to deliver low flow oxygen, while sampling part of the patients exhaled gas.

The SOFTECH Plus $ETCO_2$ Cannula has a split nare blank with oxygen delivery through one nasal prong while allowing sampling of the patient's exhaled gas from the corresponding nasal prong.

### G. Indications for Use

The Hudson RCI SOFTECH® Plus $ETCO_2$ Nasal Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen to a patient while providing a means to sample expired gas. It is intended for use in patients requiring oxygen therapy to improve blood oxygen levels while monitoring expired gas to determine ventilatory rate.

## H. Technological Characteristics Comparison to the predicate

The proposed SOFTECH Plus $ETCO_2$ Cannula is substantially equivalent to the predicate device listed above in that the indications for use, the intended use, and fundamental scientific technology remain unchanged. **Table 011.1** summarizes the differences between the proposed and predicate devices (full substantial equivalence discussion can be found in **Section 014 – Substantial Equivalence Discussion** of this submission).

**Table 011.1 - Differences Between the Proposed and Predicate Devices**

| Features | Predicate K132946 SOFTECH® Plus $ETCO_2$ Cannula | Proposed SOFTECH® Plus $ETCO_2$ Cannula | Performance Testing |
|---|---|---|---|
| **Shelf-Life** | None | 1 year Shelf-life | $ETCO_2$ Performance Testing with Simultaneous Oxygen Delivery after simulated 1 year aging |
| **Material – Oxygen Connector** | PVC, Non-DEHP | PVC, Non-DEHP (softer durometer) | Connector Performance Testing (Leak and Disconnection testing) |

## I. Performance Data

The proposed device was tested for $ETCO_2$ sampling at various oxygen flow rates after simulated 1 year aging per ASTM F1980-07 – Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices. The test results demonstrate that the device is substantially equivalent to the predicate device.

The proposed device was tested to ensure the material change did not impact the strength or performance of the oxygen connector after a material change. The test results demonstrate that the device is substantially equivalent to the predicate device. Note: No biocompatibility testing was performed as the material was previously cleared in K132946 for the same contact type and duration (see **Section 019 – Biocompatibility** of this submission for further information).

The tests performed are summarized in **Table 011.2** below.

**Table 011.2 – Performance Testing Summary**

| General Description |
|---|
| $ETCO_2$ performance in simulated conditions at various oxygen flow rates |
| Connector performance in simulated conditions |

## J. Conclusion

The device data and test results demonstrate that the device is substantially equivalent to the predicate device.